

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, ASTRAZENECA AB,
ASTRAZENECA UK LIMITED, and
ASTRAZENECA PHARMACEUTICALS
LP,

Plaintiffs,

v.

SIGMAPHARM LABORATORIES, LLC, et
al.,

Defendants.

Civil Action No. 1:15-cv-1000-RGA
CONSOLIDATED

MEMORANDUM OPINION

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February 17, 2017


ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 6,525,060 (“the ’060 patent”) and 7,265,124 (“the ’124 patent”).¹ The Court has considered the Parties’ Joint Claim Construction Brief. (Civ. Act. No. 15-1000-RGA, D.I. 149). The Court heard oral argument on February 14, 2017.

I. BACKGROUND

This litigation arises from each of the Defendants filing an Abbreviated New Drug Application (“ANDA”) before expiration of several of AstraZeneca’s patents. (D.I. 149 at 11). On October 30, 2015, Plaintiffs filed suit against each Defendant alleging that the generic products that are the subjects of the ANDA filings would infringe five of AstraZeneca’s patents. (D.I. 1).² The patents-in-suit claim chemical compounds as well as processes for making the compounds and methods for therapeutic treatments using the compounds.

II. LEGAL STANDARD

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the

¹ The ’060 patent recently reissued as U.S. Patent No. RE46,276 (“the ’276 patent”). The ’060 and ’276 patents share identical specifications except for an amended priority statement, and the asserted claims are unchanged. (D.I. 149 at 11).

² The cases have been consolidated for the purposes of pre-trial matters, including claim construction, and the trial on validity. (D.I. 25 at 4).

literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

“[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic

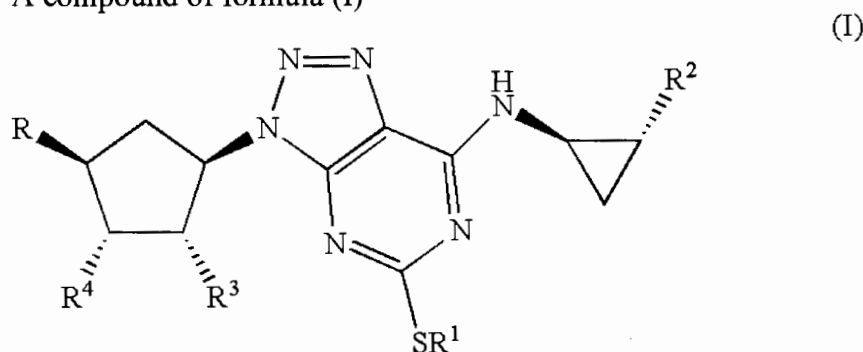
evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GMBH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

The '060 patent is directed to triazolo[4,5-d]pyrimidine compounds, processes for producing such compounds, and methods of treatment using such compounds. Claim 1 is representative and reads as follows:

1. A compound of formula (I)



wherein:

R¹ is C₃₋₅ *alkyl* optionally substituted by one or more halogen atoms;

R² is a phenyl group, optionally substituted by one or more fluorine atoms;

R³ and R⁴ are both hydroxy;

R is XOH, where X is CH₂, OCH₂CH₂ or a bond;

or a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt provided that:

when X is CH₂ or a bond, R¹ is not propyl;

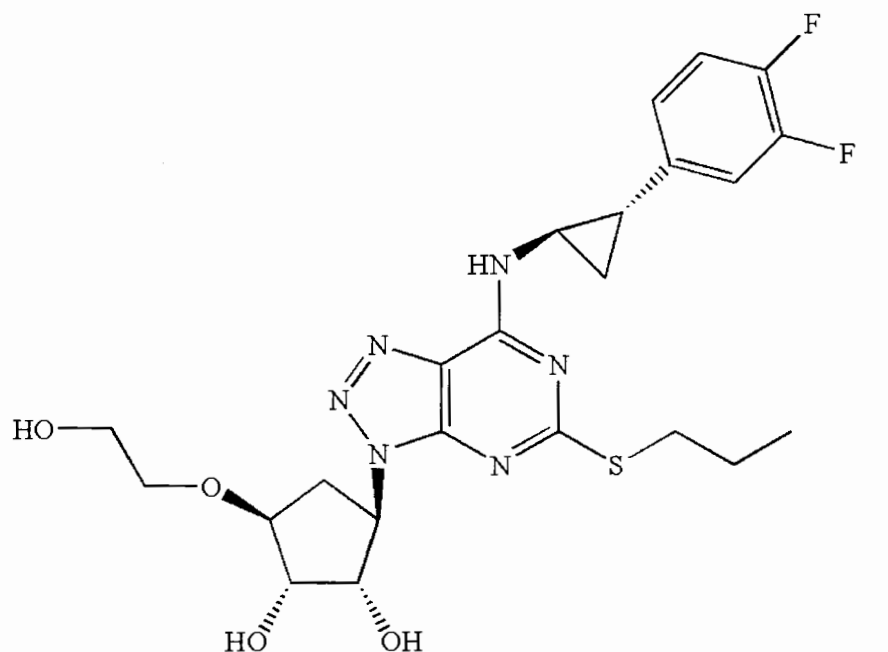
when X is CH₂ and R¹ is CH₂CH₂CF₃, butyl or pentyl, the phenyl group at R² must be substituted by fluorine;

when X is OCH₂CH₂ and R¹ is propyl, the phenyl group at R² must be substituted by fluorine.

('060 patent, claim 1) (disputed term italicized).

The '124 patent is directed to crystalline and amorphous forms of a chemical compound, processes for producing this compound, and methods of treatment using this compound. Claim 1 is representative and reads as follows:

1. A compound of formula (I):



selected from:

a compound of formula (I) characterised by an X-ray powder diffraction pattern containing *specific peaks of high intensity* at $5.3^\circ (\pm 0.1^\circ)$, $20.1^\circ (\pm 0.1^\circ)$, $20.7^\circ (\pm 0.1^\circ)$, $21.0^\circ (\pm 0.1^\circ)$ and $21.3^\circ (\pm 0.1^\circ)$ 2θ ;

a compound of formula (I) characterised by an X-ray powder diffraction pattern containing *specific peaks of high intensity* at $5.5^\circ (\pm 0.1^\circ)$, $13.5^\circ (\pm 0.1^\circ)$, $18.3^\circ (\pm 0.1^\circ)$, $22.7^\circ (\pm 0.1^\circ)$ and $24.3^\circ (\pm 0.1^\circ)$ 2θ ;

a compound of formula (I) characterised by an X-ray powder diffraction pattern containing *specific peaks of high intensity* at $14.0^\circ (\pm 0.1^\circ)$, $17.4^\circ (\pm 0.1^\circ)$, $18.4^\circ (\pm 0.1^\circ)$, $21.4^\circ (\pm 0.1^\circ)$ and $24.1^\circ (\pm 0.1^\circ)$ 2θ ; and

a compound of formula (I) characterised by an X-ray powder diffraction pattern containing *specific peaks of high intensity* at $4.9^\circ (\pm 0.1^\circ)$, $9.2^\circ (\pm 0.1^\circ)$, $11.6^\circ (\pm 0.1^\circ)$, $15.6^\circ (\pm 0.1^\circ)$ and $16.4^\circ (\pm 0.1^\circ)$ 2θ .

('124 patent, claim 1) (disputed terms italicized).

1. "C₃₋₅ alkyl"
 - a. *Plaintiffs' proposed construction*: "Straight chained and fully saturated alkyl group having 3, 4, or 5 carbon atoms"

- b. *Defendants' proposed construction:* "Plain and ordinary meaning."
- c. *Court's construction:* "Straight chained and fully saturated alkyl group having 3, 4, or 5 carbon atoms"

The only dispute between the parties with respect to this term is whether "C₃₋₅ alkyl" includes branched alkyls or whether it is limited, in the context of this patent, to straight chained alkyls. The parties agree that the plain and ordinary meaning of the term would include the branched alkyls; Plaintiffs, however, argue that the specification unambiguously defines "C₃₋₅ alkyl" to be limited, in the context of this patent, to straight chained, fully saturated alkyl groups. (D.I. 149 at 17). Defendants counter that the definition Plaintiffs point to is an exemplary embodiment rather than a definition. (*Id.* at 20).

I agree with Plaintiffs. The specification provides a figure depicting the chemical structure of the compounds claimed, followed by a series of definitional statements specifying which R groups are included in the scope of the invention. ('060 patent at 2:20-46). One of these statements calls for one of the R groups to be "C₃₋₅ alkyl." (*Id.*). As part of this definition, the specification provides, "Alkyl groups, whether alone or as part of another group are straight chained and fully saturated." (*Id.* at 2:45-46). Defendants agree that most of the language cited above is definitional, but argue that the last statement is exemplary rather than definitional. (D.I. 149 at 20-21). I disagree. It seems clear to me that this language is intended to define what is meant by "C₃₋₅ alkyl" in the context of the claimed compound. The four statements following the definition of "C₃₋₅ alkyl" begin with the words "[s]uitably" or "[p]referably," indicating that the inventor was referring in those statements to exemplary embodiments. ('060 patent at 2: 47-56). The definition of "C₃₋₅ alkyl" is not preceded by any words indicating that it is anything other than a definition intended to apply generally to the compound claimed in this patent. Therefore, I will adopt Plaintiffs' proposed construction.

2. “specific peaks of high intensity”

- a. *Plaintiffs’ proposed construction*: “Peaks in the X-ray powder diffraction pattern of a compound of formula (I) at the recited positions having high relative intensities, which together are characteristic of a crystalline form”
- b. *Defendants’ proposed construction*: “Indefinite”
- c. *Court’s construction*: “Peaks in the X-ray powder diffraction pattern of a compound of formula (I) at the recited positions having high relative intensities, which together are characteristic of a crystalline form”

Defendants argue that this term is indefinite because its meaning “is purely subjective and inherently arbitrary.” (D.I. 149 at 66). I disagree. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The claim term must be considered in the context in which it is used in the claim as well as in the context of the patent’s specification. Here, the term is not isolated when used in the asserted claims; rather, the rest of the claim provides context for what is meant. For example, claim 1 of the ’124 patent reads, in part, “a compound of formula (I) characterised by an X-ray powder diffraction pattern containing specific peaks of high intensity at 5.3° ($\pm 0.1^{\circ}$), 20.1° ($\pm 0.1^{\circ}$), 20.7° ($\pm 0.1^{\circ}$), 21.0° ($\pm 0.1^{\circ}$) and 21.3° ($\pm 0.1^{\circ}$) 2θ .” In other words, the claim specifies which peaks must be present in the diffraction pattern. The specification refers to this compound as Polymorph I and lists the same “specific peaks of high intensity” as those listed in the claims. (’124 patent at 3:48-52). The specification also includes a longer list of “specific peaks” that the diffraction pattern “[m]ore preferably” contains. (*Id.* at 3:52-57). It seems to me that the first list of “specific peaks of high intensity” refers to the most prominent peaks present in a typical diffraction pattern for this compound and the second list, with the additional peaks, includes other peaks that are of relatively

lower intensity that may not be distinguishable in every X-ray diffraction pattern. This interpretation is supported by Figure 1.1, which shows the diffraction pattern for Polymorph I, in which the peaks listed in the claim are those with the highest relative intensity. In light of the intrinsic evidence, I think a person of ordinary skill in the art would have no difficulty understanding the scope of the invention. Therefore, I will adopt Plaintiffs' proposed construction.